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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Formerly Nonprescription Drug Manufacturers Association

Comments on FDA's Request for Input
on
Changes to the Agency's General Health Claim Regulations
for Dietary Supplements that May Be Warranted in Light of the Court Decision
in *Pearson v. Shalala*
[Docket No. 00N-0598]

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The Consumer Healthcare Products Association (CHPA) is the 119-year-old trade organization representing manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research testing, and advertising sectors of the self-care industry. CHPA provides these comments as responses to FDA's questions for the invited panelists at the April 4, 2000 public meeting on health claims (1). Dr. Soller is an invited speaker on the afternoon panel addressing the third question.

Question #1: ***If health claims are allowed on a basis other than significant scientific agreement, (a.) what should that basis be and (b.) what are appropriate criteria for making decisions about scientific soundness of such claims?***

(a.) **The Truthfulness of the Claim as the Basis for Health Claims:** Health claims should be based on a standard that is consistent with the statutory provisions of the Food Drug Cosmetic Act (FDC Act), the Nutrition Labeling and Education Act (NLEA), and the *Pearson* Decision. As stated, however, FDA's question assumes that significant scientific agreement is to be defined per the agency's recent guidance on significant scientific agreement (2), which is inconsistent with the *Pearson* Decision. FDA's guidance definition of significant scientific agreement focuses on the validity of the substance-disease relationship as the decision point, when in fact based on *Pearson* and NLEA the focus should be the claim that characterizes the relationship.

Specifically, the basis for the significant scientific standard for health claims should be consistent with:

- The statutory provisions that food claims must be neither false nor misleading;
- The provision of Section 403(3)(B)(i) of the act permits FDA to promulgate regulations authorizing health claims based on "the totality of the publicly available

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scientific evidence...that there is significant scientific agreement...that the claim is supported by such evidence";

- Health claims are intended to characterize the relationship of a substance to a disease or health-related condition (3). It is not mandated by the Act that health claims for dietary supplements must represent that the relationship is so secure as to be unlikely to be overturned by future research. Such a standard would be unreasonably high, given the evolving nature of scientific understanding. Rather, health claims "characterize the relationship," meaning such characterization may be made in the context of qualifier or disclaimer (see immediately below); and
- The Pearson Decision, which upholds the following:
  - "Truthful" promotion that is "related to lawful activities" is "entitled to the protections of the First Amendment;"
  - FDA "may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive;"
  - The "preferred remedy" for a potentially-misleading statement "is more disclosure, rather than less;"
  - The use of promotional information with "disclaimers" is "constitutionally preferable to outright suppression."

Thus, *Pearson* maintains that both qualifiers and disclaimers may be considered as a means to characterize a health claim.

Hence, health claims must be allowed on the basis of significant scientific agreement that addresses truthful representation in labeling of the available scientific evidence concerning a substance-disease relationship.

FDA's Guidance to Industry Misses the Mark: On December 22, 1999, FDA issued a guidance with a request for comments on its definition of significant scientific agreement. In that guidance FDA sets forth "the standard of scientific validity" based on (1) "the totality of the publicly available evidence support[ing] the substance/disease relationship that is the subject of the claim; and (2) existence of significant scientific agreement among qualified experts that the relationship is valid." FDA states that "the standard of scientific validity" is a "strong standard that provides a high level of confidence" that "the relationship is not likely to be reversed by new and evolving science."

FDA's creation of "the standard of scientific validity" as an approach of responding to the *Pearson* Decision to define significant scientific standard indicates that the agency either does not understand the intent of the Court or is unwilling to follow its dictate. If the standard for a health claim is so high as to be not reversed by evolving science, why then would the Court permit the use of qualifier? FDA's definition of "the standard of scientific validity" to replace statutory requirement of "significant scientific agreement" is not better than word-smithing FDA's original position before the Court.

ACTION REQUESTED: CHPA requests that FDA retract its guidance on significant scientific agreement and adopt one that is statutorily based and expresses the intent of *Pearson* Decision, such as outlined in the FTC's "Dietary Supplements: An Advertising Guide for Industry."

(b.) **Criterion for Making Decisions About the Scientific Soundness of the Claim:** The criterion for the scientific soundness of the claim is a determination that the that the label claim must not be false or misleading – in essence a "truth-in-labeling-standard," not unlike FTC's truth-in-advertising standard."

Specific characteristics of how a claim may be constructed to meet a "truth-in-labeling standard" through the use of a qualifier or disclaimer are discussed in CHPA's answer to question #2.

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Question #2: ***If health claims for dietary supplements are to be appropriately qualified or disclaimed so that consumers are not misled, what should be the characteristics of such disclaimers?***

The *Pearson* decision clarifies that FDA should consider both qualifiers and disclaimers as approaches to allowing health claims. While *Pearson* does not define a qualifier or a disclaimer, it is clear that the Court understood that they are different, since the summary decision provided a distinct and very different example for each.

- A qualifier modifies a particular statement in a way that ensures its limitations are understood, as for example, a statement might qualify that the substance is effective in disease risk reduction for a subset of the general population. The example provided in *Pearson*: "The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risks of cancer may result from other components of foods."

- A disclaimer does more than modify a statement, since it is also a denial or disavowal of ownership of a statement, such as the statutory disclaimer for structure/function claims. The example provided in *Pearson* is: "FDA does not approve this claim."

The Federal Trade Commission has already addressed the issue of the characteristics of disclaimers and qualifiers to assess the truthfulness of a dietary supplement claim (4).

First, the substantiating evidence should provide a reasonable basis for making the claim. A "reasonable basis," per FTC's guide, "depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified," yet it should be "flexible to ensure that consumers have access to information about emerging areas of science ...[and]... sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented..."

Then, if a qualifier or disclaimer is to be used, it should be:

- Clear, simple, and prominent;
- Able to be understood in terms of the extent of the scientific support and the existence of any significant contrary evidence; and
- Based on studies and other support that is a stronger body of evidence any contrary information.

ACTION REQUESTED: CHPA requests FDA to adopt FTC's "Dietary Supplements: An Advertising Guide for Industry" as a framework for creating a guidance on significant scientific agreement for the purposes of health claims.

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Question #3: ***(a.) Should health claims go beyond claims that relate to risk reduction within the normal, healthy population and now include claims targeted toward mitigation and treatment of disease symptoms among population groups with the existing disease conditions? (b.) Where is the boundary, if any, between the claims?***

(a.) Yes, health claims should include claims targeted toward mitigation and treatment of disease symptoms. Health claims relating to disease treatment is an issue with potentially great public health benefits. Importantly, it bears a clear relation to the *Pearson* Decision which concludes that "truthful" promotion that is "related to lawful activities" is "entitled to the protections of the First Amendment" (see above), notwithstanding the fact that *Pearson* did not address "treatment health claims." By law and regulation, a health clam means "any claim made on the labeling of a food including a dietary supplement that expressly or by implication ... characterizes the relationship of any substance to a disease or health related condition." [§ 101.14(a)(1)] A truthful statement, even if qualified, about how a substance may treat a disease is a characterization of that substance's relationship to the disease under consideration.

To date, health claims authorized by FDA have been for reducing the risk of disease in the general population. An example of such a claim is that published by FDA in *FDA Consumer*:

> "Sample Claim: Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life."(5)

However, treatment of osteoporosis, while requiring a diagnosis, includes calcium supplementation. Indeed, the efficacies of currently used prescription drugs are based, in the main, on use with concomitant calcium supplementation. (6) Hence, truthful and not misleading information on the label of calcium supplements about the use of calcium in the overall treatment of osteoporosis, in addition to calcium's role in the prevention of osteoporosis, would be an important public health outreach to a vulnerable population. Indeed, such a treatment claim for calcium for osteoporosis could be qualified to recommend a physician visit to determine whether the potential product user was suffering from the disease. Note that in the OTC arena, FDA permits self care products with labeling recommending physician diagnosis before use (e.g., bronchodilators for use in asthma; antifungals for use in vaginal candidiasis), and such labeling was undertaken at the discretion of the agency, entirely within existing laws and regulations.

Furthermore, calcium has recognized nutritive value. Hence, the potential conundrum that FDA describes in the *Federal Register* announcing the April 4th meeting on *Pearson* and health claims [i.e., that pertaining to FDA's requirement that for a product to bear a health claim, it must establish that it is a food by demonstrating nutritive value; 21 CFR 101.14(b)(3)], is self-resolvable in this instance. As other dietary supplements with known nutritive value have scientific evidence gathered to support treatment of disease (e.g., vitamin D and calcium in conjunction with prescription drug therapy for

osteoporosis; Omega-3 fatty acids, folic acid, B-complex and possibly others for heart disease, etc.), it would make sense to have a mechanism available to provide consumer access to FDA-authorized information on important health/disease and diet-related issues. If the agency is concerned that patients may forego prescription drug treatment for dietary supplements, then as needed such a concern could be the basis for a qualifier on the treatment-health claim for dietary supplements.

However, as logical as this sounds, the issue of nutritive value becomes a stumbling stone when considering health claims for dietary supplements which do not have a documented nutritive value. As defined by FDA in the final rule: "Nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy."(7) At the time of that proposed rule, the agency received many comments expressing concern that the definition of nutritive value was potentially too narrow. However, the agency in answering these concerns stated:

> "As FDA explained in the health claims final rule (58 FR 2478 at 2488), the definition of 'nutritive value' is intended to be very flexible. The agency incorporated this flexibility in the definition because FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. FDA believes that the agency should evaluate the nutritive value claimed for a substance that is proposed as the subject of a health claim, as described in a health claim petition, on a case-by-case basis. This approach will best ensure that the definition retains its intended flexibility and does not become an unintentional barrier to authorization for legitimate health claims."

However, the agency also stated the following, which creates the current apparent conundrum when considering a dietary supplement such as saw palmetto for treatment of benign prostatic hypertrophy as one having a documented nutritive value:

> "In general, the agency will look for evidence that the claimed effect on disease is associated with the normal maintenance of human existence. If the substance is used to correct an abnormal physiological function caused by a disease or health-related condition, the action of the substance is clearly beyond a normal maintenance function, and the health benefit would therefore not derive from the substance's nutritive value." (*Federal Register* 59: 407, 1994)

ACTION REQUESTED: Diet/disease treatment relationships can be a logical health-based extension of dietary supplement function. FDA's recognition of this issue carries First Amendment implications. Therefore, it would be sound public policy to amend the health claim regulations to permit such claims. In so doing, FDA should redefine nutritive value, so as to recognize that the processes by which a dietary constituent promotes health, maintains proper bodily functioning, protects the body from the development of chronic disease or other health-related conditions, and facilitates and/or restores healthy functioning are, in and of themselves, characteristic of "nutritive value," thereby creating a more logically flexible approach to health claims.

Further, FDA could stipulate specific criteria that might be considered as part of a "disease treatment-related health claim," including documentation of safe use for treatment of the specific disease under consideration, consideration of how labeling

addresses informing consumers of adequate diagnosis to optimize treatment, among other things.

Importantly, because of the authorization procedure for health claims, FDA maintains control of the claims environment to ensure the claims are truthful and not misleading, and if necessary appropriately accompanied by a qualifier or disclaimer.

Finally, by allowing health claims for disease treatment for dietary supplements, FDA would create a regulatory mechanism that would provide a means to create a generic authorized (or approved) claim for a dietary supplement or food that might have been tested for disease treatment in an NIH trial (i.e., not company sponsored), as may be the case for St. John's wort which is under study by NIH for depression.

(b.) Comment on "Boundaries": The issue of boundaries is more of a distraction than a helpful concept when considering disease-treatment health claims for dietary supplements. This is because, by law and regulation, a health clam means "any claim made on the labeling of a food including a dietary supplement that expressly or by implication ... characterizes the relationship of any substance to a disease or health related condition." [§ 101.14(a)(1)] A truthful statement, even if qualified, about how a substance may treat, cure, mitigate or diagnose a disease is a characterization of that substance's relationship to the disease under consideration. Hence, FDA should be less worried about artificial boundaries and more concerned about authorizing truthful information about relationships between dietary supplements and diseases.

ENDNOTES

1. See Federal Register Announcement of March 13, 2000 re: Docket No. 00N-0598.
2. FDA: Guidance for industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements. December 22, 1999.
3. Under § 101.14 (a) (1), a health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.
4. FTC: Dietary Supplements: An Advertising Guide for Industry. http://www.ftc.gov/
5. U.S. Food and Drug Administration: Health Claims - FDA Consumer: Staking a Claim to Good Health: FDA and Science Stand Behind Health Claims on Foods. FDA Consumer November - December 1998.
6. FDA Division of Metabolic and Endocrine Drug Products: Guidelines for preclinical and clinical evaluation agents used in the prevention or treatment of postmenopausal osteoporosis. Page 16, April, 1994.
7. FDA: Food Labeling; General Requirements for Health Claims for Dietary Supplements: Final Rule. Federal